22. The method of Claim 13, wherein the pharmaceutical composition further comprises a buffer.
23. The method of claim 13, wherein the composition is administered at a dose effective to target blood glucose levels from about 4.1 mM to 7.5 mM.
24. The method of claim 14, wherein the compound is administered at a dose effective to target blood glucose levels from about 4.1 mM to 7.5 mM.
25. The method of claim 16, wherein the compound is administered at a dose effective to target blood glucose levels from about 4.1 mM to 7.5 mM.
26. The method of claim 20, wherein the peptide is selected from the group consisting of GLP-1, GLP-1 analogs, and GLP-1 derivatives and is administered at a dose effective to target blood glucose levels from about 4.1 mM to 7.5 mM.

Remarks

Claim 13 is amended by deleting "a buffer, and a preservative." Claim 18 is a dependent claim of claim 13 and is amended to correct the antecedent basis. Claim 22 is a dependent claim of claim 13. Claims 23-26 are dependent claims of claim 13, 14, 16, and 20. Basis for claim 22 can be found on page 33, lines 33-36. Basis for the new claims 23-26 can be found on page 21, Table 1.

ELECTION/RESTRICTION

The amendment to claim 20 has made the restriction requirement moot. The Examiner is thanked for making this claim generic to the invention of Group I.

REJECTION UNDER 35 U.S.C. § 112

The Examiner rejected Claim 13 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amended claim 13, thus rendering the rejection moot.

REJECTION UNDER 35 U.S.C. § 112

The Examiner rejected Claim 20 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree with the

Examiner that there is no basis for the focus on 'peptides.'" Basis for "peptide" is disclosed throughout Applicants specification. As evidenced by the following excerpts from the specification, Applicants clearly contemplated the use of peptides that interact with the GLP-1 receptor in the claimed method.

> The use of -GLP-1 type molecules for prolonged therapy of diabetes has been obstructed because the serum half-life of such *peptides* is quite short. (page 4, lines 4-6).
>
> Such molecule is selected from the group consisting of a *peptide* . . . (page 8, lines 37-38; page 10, lines 13-14).
>
> [A] derivative of said *peptide*, wherein said *peptide* is selected from the group consisting of: a pharmaceutically-acceptable acid addition salt of said *peptide*; a pharmaceutically-acceptable carboxylate salt of said *peptide*; a pharmaceutically-acceptable lower alkylester of said *peptide*; and a pharmaceutically-acceptable amide of said *peptide* selected from the group consisting of amide, lower alkyl amide, and lower dialkyl amide. (page 9, lines 8-15; page 10, lines 22-29).
>
> Solid phase chemical synthesis of *polypeptides* is well known in the art (page 11, lines 13-14).
>
> For example, the amino acid portion may be synthesized by solid-phase methodology utilizing a 430A *peptide* synthesizer (page 11, lines 20-22).
>
> Following completion of the synthesis the *peptides* may be deprotected and cleaved from the resin with anhydrous hydrogen fluoride (HF) containing 10% meta-cresol. Cleavage of the side chain protecting group(s) and of the *peptide* from the resin is carried out at -5 0 C to 50C, preferably on ice for 60 minutes. After removal of the HF, the *peptide*/resin is washed with ether, and the *peptide* extracted with glacial acetic acid and lyophilized. (page 12, lines 1-8).
>
> Having constructed an expression vector for the amino acid portion of a compound used in the present invention, the next step is to place the vector into a suitable cell and thereby construct a recombinant host cell useful for expressing the *polypeptide*. (page 14, lines 34-38).
>
> The *peptide* can be acylated either before or after the imidazolic group is added. Moreover, if the *peptide* is prepared recombinantly, acylation prior to enzymatic cleavage is possible. (page 15, lines 27-30).

The Examiner also stated that the claims directed to peptide agonists of the GLP- 1 receptor which are not GLP- 1, GLP- 1 analogs, or GLP- 1 derivatives lack an adequate written description. Applicants respectfully disagree with the Examiner's assessment of

Applicant's invention. The specification discloses thousands of peptides that interact with the GLP-1 receptor beginning on page 5 of the specification. In addition, the receptor was known and characterized before Applicants' filing date. The full-length human GLP-1 receptor sequence was published as early as 1993. (Dillon et al. (1993) Cloning and Functional Expression of the Human Glucagon-like Peptide-1 (GLP-1) Receptor, *Endocrinology,* 133:1907-1910.) Further, several articles were published before Applicants' filing date describing structure-activity studies with various peptides that interact with the GLP-1 receptor.

(1) Adelhorst et al. (1994) Structure-Activity Studies of Glucagon-like Peptide-1, J. *Biol. Chem.* 269: 6275-6278.
(2) Hjorth et al. (1994) Glucagon and Glucagon-like Peptide 1: Selective Receptor Recognition via Distinct Peptide Epitopes, *J. Biol. Chem.* 269: 30121-30124.
(3) Gallwitz et al. (1996) GLP-1/G1P Chimeric Peptides Define the Structural Requirements for Specific Ligand-Receptor Interaction of GLP-1, *Regulatory Peptides* 63: 17-22.
(4) Mojsov et al. (1992) Structural Requirements for Biological Activity for Glucagon-like Peptide-I, *Int. J. Peptide Protein Res.*. 40:333-343.
(5) Gallwitz et al. (1994) Structure/Activity Characterization of Glucagon-like Peptide-1, *Eur. J. Biochem.,* 225:1151-1156.

Thus, the structure of the receptor coupled with the thousands of known peptides that interact with the GLP-1 receptor adequately describes a new use for a generic class of peptides that interact with the GLP-1 receptor.

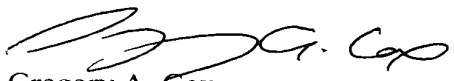
There is no requirement in the United States patent laws for a patent to describe and exemplify each and every compound falling within the scope of a claimed use. It would be wholly unreasonable to require Applicants to describe in page after page of description all the compounds known to fall within the class of compounds defined to fall within the claimed use. Likewise, it would be unreasonable to limit the claims to only those compounds described specifically or exemplified in specific examples.

NONSTATUTORY DOUBLE PATENTING REJECTION

Applicants note the Examiner's nonstatutory double patenting rejection of Claims 13-19. The conflicting patent is commonly owned with this application. Applicants will consider filing a terminal disclaimer once claims are in allowable form.

If the Examiner feels that a telephone conversation with Applicants' Attorney would be helpful in expediting the prosecution of this case, the Examiner is urged to call Applicants' Attorney at (317) 277-2620.

Respectfully submitted,



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May 12, 2003